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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,439	01/22/2004	Paul Ashton	CDSI-P01-041	5180

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1609	

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05/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,439	ASHTON ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *4-9 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,10 and 14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/30/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

Response to Election/Restriction

1. Applicant's election with traverse of Group I in the response to restriction requirement filed on 05/14/2007 is acknowledged. Group I contains claims 1-3, 10, and 14-21 drawn to a sustained release drug delivery device. The traversal is on the ground(s) that the simultaneous examination of Group II, drawn to a method that utilizes the device of claim 1, would not present a significant search burden. This is not found persuasive because as stated in the restriction requirement, the sustained release drug delivery device can be used in a materially different process of using the device, for example it can be used to treat migraine headaches or anxiety. The search involved for the process of using the sustained release drug delivery device would be different from the search for the sustained release drug delivery device.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 4-9, and 11-13 are not elected.

3. Claims 1-3, 10, and 14-21 are being presented for examination.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 08/30/2004 was filed. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. See attached copy of PTO-1449.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 10, 14-15, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,378,475).

The claimed invention is a sustained release drug delivery device for insertion or implantation in or adjacent to the eye of a patient comprising an inner drug core comprising an adrenergic agent, a first coating, and one or more additional coating layers which allow the sustained release of the adrenergic agent.

Smith teaches a sustained release drug delivery device including an inner core or reservoir with the active ingredient and coating layers (Abstract). The first coating layer is "essentially impermeable to the passage of the effective agent, and a second coating permeable to the passage of the effective agent" (Col. 1, lines 6-12). The invention includes "an ocular device suitable for direct implantation into the vitreous of the eye" which provides "sustained controlled release of various compositions to treat the eye without risk of detrimental side effects" (Col. 3, lines 38-43). Further, Smith teaches that "the devices are particularly suitable for treating ocular conditions such as glaucoma" (Col. 5, lines 28-29). Antiglaucoma drugs such as timolol and betaxolol are disclosed as components of the inner core of the device (Col. 5, lines 51-52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sustained release drug delivery device for an ocular implant by using the anti-glaucoma drugs, as suggested by Smith, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Smith teaches using the device for treating glaucoma. One of ordinary skill in the art would use the adrenergic agents in the device to treat high ocular pressure that is associated with glaucoma. As mentioned earlier, the device allows sustained controlled release of the active "without risk of detrimental side effects" (Col. 3, lines 40-43).

Regarding instant claims 1-2, 14 the limitations of a sustained release drug delivery device for implantation in the eye, an inner core comprising an adrenergic agent, a first coating that is substantially impermeable to the passage of the adrenergic agent, one or more additional coatings that are permeable to the passage of the adrenergic agent would have been obvious to one skilled in the art over the sustained release drug delivery device for an ocular implant teaching of Smith. Smith teaches a first coating layer that is "essentially impermeable to the passage of the agent" and a second coating layer that is "permeable to the passage of the agent" (Col. 3, lines 15-29). The first coating layer being impermeable to the passage of the agent, controls "the release of the agent out of the drug delivery device" (Col. 7, lines 10-15).

The limitations of the impermeable coating having sufficient dimensional stability of instant claims 2 and 3 would have been obvious to one skilled in the art given the teaching in Smith that "devices formed of polymeric materials that are insoluble in tear

fluid retain their shape and integrity during the course of the needed therapy ..." (Col. 2, lines 18-21). "Materials that may be suitable for fabricating the fist or second coating layer of the device include naturally occurring or synthetic materials that are biologically compatible with body fluids and eye tissues, and essentially insoluble in body fluids with which the material will come in contact" (Col. 6, lines 30-35). Therefore, a person skilled in the art would find that an ocular implant device comprised of coating materials that are insoluble in eye fluids would retain its shape and integrity during the course of therapy.

The limitation of adrenergic agents of instant claim 10 would have been obvious to one skilled in the art given the timolol and betaxolol disclosed as components of the inner core of the device by Smith (Col. 5, lines 51-52).

The limitation of the inner drug core admixed with a polymer matrix of instant claim 15 would have been obvious to one skilled in the art given the materials taught by Smith. Smith teaches, "naturally occurring or synthetic materials that are biologically compatible with body fluids and eye tissues and essentially insoluble in body fluids which the material will come in contact include, ... polyvinyl acetate ..." (Col. 6, lines 41-66).

The limitation of co-extruding the inner drug core and the coating layer of instant claim 17 would have been obvious to one skilled in the pharmaceutical art of process and product development. In order to have the drug core coated by the polymer matrix, co-extrusion is an obvious method used in the art.

3. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,378,475) in view of Wong et al. (US 6,331,313).

The teaching of Smith is stated above.

Smith does not expressly teach a bioerodible polymer matrix.

Wong teaches a controlled release biocompatible ocular drug delivery device that can be implanted in the eye (Abstract). The device comprises "a substantially impermeable polymeric outer layer covering a core which comprises the drug to be delivered ..." (Col. 1, lines 56-59). The device "is implanted in the eye to treat or prevent a variety of conditions of the eye such as ... ocular pressure..." (Col. 8, lines 12-15).

The limitation of the bioerodible polymer matrix of instant claim 16 would have been obvious to one skilled in the art over the materials taught by Wong. Wong teaches examples of biodegradable polymers that can be used in the device where "the outer layer degrades after the drug has been released for the desired duration" (Col. 9, lines 43-45 and lines 60-67, Col. 10, lines 1-9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sustained release drug delivery device for an ocular implant by using the anti-glaucoma drugs, as suggested by Smith, and combine it with the biodegradable polymers taught by Wong, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the outer layer of the device "degrades after the drug has been released for the desired duration" (Wong, Col. 9, lines 43-45).

4. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 5,902,598).

Chen teaches sustained release drug delivery devices "suitable for treating ailments affecting the eye" (Col. 2, lines 5-6). An "ocular device suitable for direct implantation into the vitreous of the eye" which provides "sustained controlled release of various compositions to treat the eye without risk of detrimental side effects" (Col. 4, lines 6-11). The "device includes an inner core or reservoir which contains an agent effective in obtaining a desired effect. The device further includes a first coating layer, a second coating layer and a third coating layer. The first coating layer ... is permeable to the passage of the effective agent ..." (Col. 4, lines 53-58). The device is "particularly suitable for treating ocular conditions such as glaucoma ..." (Col. 5, lines 65-66). Antiglaucoma drugs such as timolol and betaxolol are disclosed (Col. 6, lines 17-18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sustained release drug delivery device for an ocular implant, as suggested by Chen, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Chen teaches using the device for treating glaucoma and includes adrenergic agents timolol and betaxolol. One of ordinary skill in the art would use the adrenergic agents in the device to treat high ocular pressure that is associated with glaucoma. Chen teaches a device that allows sustained controlled release of the active "without risk of detrimental side effects" (Col. 4, lines 6-11).

The limitation of the inner drug core admixed with a polymer matrix of instant claim 19 would have been obvious to one skilled in the art given the materials taught by Chen. Chen teaches, "naturally occurring or synthetic materials that are biologically compatible with body fluids and eye tissues and essentially insoluble in body fluids which the material will come in contact include, ... polyvinyl acetate ..." (Col. 7, lines 1-14).

5. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 5,902,598) in view of Wong et al. (US 6,331,313).

The teaching of Chen is stated above.

Chen does not expressly teach a bioerodible polymer matrix.

Wong teaches a controlled release biocompatible ocular drug delivery device that can be implanted in the eye (Abstract). The device comprises "a substantially impermeable polymeric outer layer covering a core which comprises the drug to be delivered ..." (Col. 1, lines 56-59). The device "is implanted in the eye to treat or prevent a variety of conditions of the eye such as ... ocular pressure..." (Col. 8, lines 12-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sustained release drug delivery device for an ocular implant by using the anti-glaucoma drugs, as suggested by Chen, and combine it with the biodegradable polymers taught by Wong, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the outer layer of the device "degrades after the drug has been released for the desired duration" (Wong, Col. 9, lines 43-45).

The limitation of the bioerodible polymer matrix of instant claim 16 would have been obvious to one skilled in the art over the materials taught by Wong. Wong teaches examples of biodegradable polymers that can be used in the device where "the outer layer degrades after the drug has been released for the desired duration" (Col. 9, lines 43-45 and lines 60-67, Col. 10, lines 1-9).

The limitation of co-extruding the inner drug core and the coating layer of instant claim 21 would have been obvious to one skilled in the pharmaceutical art of process and product development. In order to have the drug core coated by the polymer matrix, co-extrusion is an obvious method used in the art.

Conclusion

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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